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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,050	09/27/1999	YEHUDA SHOENFELD	ZAP-1CIPCONC	9070

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/405,050	Applicant(s) Shoenfield et al
	Examiner Mark Navarro	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-11 and 22-29* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-3, 6-11, and 22-29* is/are rejected.

7) ☒ Claim(s) *4 and 5* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Additionally Applicant's amendment filed on September 10, 2001 has been entered. Consequently claims 1-11 and 22-29 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of Claims 1-11 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained is withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

2. The rejection of claims 1-2, 7-9, and 25-28 under 35 U.S.C. 102(b) as being anticipated by Chapel *et al* is maintained.

Applicant's are asserting that each of the rejected claims requires the use of IVIG or fragments thereof in the inhibition of lymphoma metastasis or treatment of metastatic lymphoma, and that such methods are not inherently performed by the prior art. Applicant's further assert that the cited references do not show inhibition of metastasis as defined by the specification, nor do they show treatment of metastatic lymphoma. Applicant's assert that the non-Hodgkin's lymphoma described in Chapel et al could have been metastatic or non-metastatic, each scenario is possible and plausible. Applicant's conclude that if there was no metastasis present, then no inhibition of metastasis can have occurred. Finally Applicant's assert that their is no disclosure in the cited references of the use of IVIG in patients with metastatic lymphoma with the intent to inhibit metastasis of the lymphoma or treat the lymphoma itself.

Applicant's arguments have been fully considered but are not found to be fully persuasive.

First, Chapel et al disclose the administration of IVIG to patients with non-Hodgkin's lymphoma. It is this administration of IVIG which inherently inhibits the metastasis of the lymphoma. As Applicant's specification points out "Metastasis" is defined as the transfer of malignant tumor cells, or neoplasm, via the circulatory or lymphatic systems or via natural body cavities, usually from the primary focus of neoplasia to a distant site in the body, and subsequent development of secondary tumors or colonies in the new location." (Page 4, lines 22-27). Applicant's further define "inhibition of metastasis" as "preventing or reducing the development of metastases." (Page 4, lines 30-31). Consequently, the administration of the IVIG inherently

"prevents" metastasis from occurring. Applicant's assert that the non-Hodgkin's lymphoma described in Chapel et al could have been metastatic or non-metastatic, each scenario is possible and plausible. However, each of these scenarios in view of the administration of IVIG, results in the inhibition of metastasis. Contrary to Applicant's assertions, no requirement for active metastasis is necessary. Furthermore, the claims do not require the added step of first determining in the lymphoma has metastatic potential, only inhibiting the metastasis of the lymphoma, which is accomplished by the addition of IVIG, exactly as disclosed by Chapel et al. The claims are directed to "inhibiting metastasis." Administering the IVIG to an individual with non-Hodgkin's lymphoma results in the inhibition of metastasis. For example the administration of an antibiotic results in the inherent inhibition of bacterial infection, regardless of whether or not a bacterial microorganism is present or not. In other words, Chapel et al inhibited both non-metastatic as well as metastatic lymphomas, as a result of administering the IVIG. Consequently, Chapel et al disclose each and every limitation of the claimed invention.

Finally, Applicant's assert that their is no disclosure in the cited references of the use of IVIG in patients with metastatic lymphoma with the intent to inhibit metastasis of the lymphoma or treat the lymphoma itself. However, the intent for the administration of the IVIG is irrelevant. The only question involved under 102 is, is each and every limitation disclosed, intent of the administration plays no role.

Chapel *et al* (Clin. Res. 1988, 36(3) page 407A) disclose of patients with low grade non-Hodgkin's lymphoma receiving intravenous immunoglobulins. (See abstract).

In view that patients with lymphoma received IVIG as claimed, the result of inhibiting metastasis of the lymphoma is deemed to be an inherent result of the administered IVIG, and consequently anticipates the claimed invention.

For reasons of record in Paper Number 9, as well as the above cited reasons this rejection is maintained.

3. The rejection of claims 1-3, 7-11, 25 and 28 under 35 U.S.C. 102(b) as being anticipated by Morell *et al* is maintained.

Applicant's assertions are essentially the same as those set forth above in paragraph 2, and have been addressed accordingly above in paragraph 2.

Morell *et al* (Pediatr. Infect Dis. J. Vol. 7, No. 5, pp S87-S91, 1988) disclose of 9 patients who were on cytostatic therapy for non-Hodgkin's lymphoma receiving 0.4g/kg of IVIG daily. Morell *et al* further set forth that of administering IVIG for greater than 5 consecutive days. (See page S90 and Figure 3).

In view that patients with lymphoma received IVIG in an amount of 2g/kg/month as claimed, the result of inhibiting metastasis of the lymphoma is deemed to be an inherent result of the administered IVIG, and consequently anticipates the claimed invention.

For reasons of record in Paper Number 9, as well as the above cited reasons this rejection is maintained.

4. The rejection of claims 1-3, 6-9, and 25-28 under 35 U.S.C. 102(b) as being anticipated by Besa *et al* is maintained.

Applicant's assertions are essentially the same as those set forth above in paragraph 2, and have been addressed accordingly above in paragraph 2.

Besa *et al* (American Journal of Medicine Apr. 1988, Vol. 84(4), pp 691-698) disclose of patients with Hodgkin's lymphoma and non-Hodgkin's lymphoma treated with intravenous immunoglobulin (0.4g/kg) daily for five doses followed by maintenance therapy every 21 to 28 days if evidence of recurrence was noted. (See abstract).

In view that patients with lymphoma received IVIG in an amount of 2g/kg/month as claimed, the result of inhibiting metastasis of the lymphoma is deemed to be an inherent result of the administered IVIG, and consequently anticipates the claimed invention.

For reasons of record in Paper Number 9, as well as the above cited reasons this rejection is maintained.

5. The rejection of claim 29 under 35 U.S.C. 102(b) as being anticipated by Vitetta *et al* is maintained.

Applicant's are asserting that Vitetta et al disclose the use of the Fab' fragment of a monoclonal anti-CD22 antibody coupled to chemically deglycosylated ricin A chain, and that this is not an IVIG as defined in Applicants' specification.

Applicant's arguments have been fully considered but are not found to be fully persuasive.

Applicant's have defined IVIG as "gamma globulin preparations suitable for intravenous use, such as those IVIG preparations commercially available from several sources."

Vitetta et al administered the immunoglobulin to patients intravenously. (See page 4053). Consequently the preparations disclosed by Vitetta et al appear to be "suitable for intravenous use" as required by the definition provided by the specification.

Vivetta *et al* (Cancer Research Vol. 51, pp 4052-4058, August 1, 1991) disclose of Fab' fragments attached to ricin A chain being administered to patients with refractory B-cell lymphomas. (See abstract).

In view that Vivetta *et al* disclose of the intravenous administration of Fab' fragments to a mammal with a B-cell lymphoma, the disclosure of Vivetta *et al* is deemed to anticipate the claimed invention.

For reasons of record in Paper Number 9, as well as those recited above, this rejection is maintained.

Claim Rejections - 35 USC § 103

6. The rejection of claims 1-3, 5-11, 22, and 25-28 under 35 U.S.C. 103(a) as being unpatentable over Morell *et al* or Besa *et al* in view of Cafiero *et al*, Webb *et al* and Way is withdrawn in view of Applicant's arguments.

Double Patenting

7. The rejection of claims 1-11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,965,130 is maintained. Additionally this rejection is applied to newly added claims 22-29.

Applicant's have indicated a willingness to filed a terminal disclaimer to overcome this rejection, however until a terminal disclaimer is filed and made of record, this rejection is maintained for reasons of record in Paper Number 9.

8. The rejection of claims 1-11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,562,902 is maintained. Additionally this rejection is applied to newly added claims 22-29.

Applicant's have indicated a willingness to filed a terminal disclaimer to overcome this rejection, however until a terminal disclaimer is filed and made of record, this rejection is maintained for reasons of record in Paper Number 9.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 112

9. Claims 22-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "A method for treating lymphoma in a mammal which comprises..." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what treatment criterium is being measured, (e.g., inhibition of metastasis, tumor regression, reduction of pain, amelioration of symptoms, etc.)? Without a clear definition as to what criterium is being measured one of skill in the art would be unable to ascertain the metes and bounds of "treating."

Claims 4-5 are objected to as depending upon a rejected base claim, however claims 4-5 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

May 1, 2002